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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/302,239	04/29/99	NELSESTUEN G	09531/005001

HM12/1205

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EXAMINER	
MOEZIE,F	

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/302,239	Applicant(s) Nelsestuen
	Examiner F. T. Moezie	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Apr 29, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-22* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

STATUS OF CLAIMS

Claims 1-22 are pending in this application.

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a modified form of Factor VII, classified in class 530, subclass 384, *for example*.

II. Claims 1-17, drawn to a modified form of Factor IX, classified in class 530, subclass 384, *for example*.

III. Claims 18 and 19, drawn to a composition comprising the modified form of Factor VII, classified in class 514, subclass 2, *for example*.

IV. Claims 18 and 19, drawn to a composition comprising the modified form of Factor IX, classified in class 514, subclass 2, *for example*.

V. Claim 20 is, drawn to the first method of treating - increasing clot formation, classified in class 514, subclass 2, *for example*.

VI. Claim 21, drawn to a second method of treating - a blood disorder, classified in class 514, subclass 2.

VII. Claim 22, drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.1, *for example*.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct one form the other. The inventions are distinct because each Factor has its own unique structure and thereby its own physicochemical - chemical properties. Therefore, each invention requires a separate manual and computer searches and a separate consideration of patentability. Moreover, a reference which would render obvious claims drawn to Factor VII may not obviate claims drawn to Factor IX, absent ancillary evidence. It would be an undue burden to examine both inventions in one application.

Inventions I, II, III or IV and V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as unmodified Factor VII or Factor IX.

Inventions I or II and VII are distinct one from the other. Inventions are distinct because they are drawn to separate inventions and they are not disclosed as capable of use together and they have different modes of operation, different functions, different structures and/or effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products can be obtained by classical chemical methods of preparing them. Furthermore, the searches are not co-extensive as indicated above. It would be an undue burden to examine the inventions in one application

Because these inventions are distinct for the reasons given ***above*** and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event applicant elects Group I or Group II invention and the claims to the elected inventions are found allowable, Examiner will consider a rejoinder of claims drawn to a composition and the first method of use provided that the claims are rewritten and are commensurate in scope with the allowable compound claims.

ELECTION OF SPECIES

Claims 1-21 are generic to a plurality of disclosed patentably distinct species comprising modified GLA domain of Factor VII or XI. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, and an ultimate specie, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention (from Group I to Group VII), an election of the species together with the election of an ***ultimate*** specie to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is further required to indicate claims that are already of record and reading on the elected species, within the elected invention, or draw new claim(s) to the elected invention - species.

An ***ultimate*** specie is a specie wherein ***all*** of the variable parameters are accounted for.

RESPONSE TO SEQUENCE LISTING REQUIREMENTS

The response to NOTICE TO COMPLY WITH THE REQUIREMENTS FOR THE AMINO ACID SEQUENCE DISCLOSURE filed 10/30/00, paper no. 9, has been considered, but not found acceptable.

Applicant is *required* to enter the SEQ ID NOS in the specification as indicated earlier, paper no. 7. The modifications could be entered into all parts of the specification and the claims, as cited earlier, following the entry of the proper SEQ ID NOS, as explained by the applicant in the second paragraph of the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T. Moezie whose telephone number is (703) 305-4578.

F.T. Moezie
T. MOEZIE, PH.
PRIMARY EXAMINER
ART UNIT 1653